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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	§	**ATTY DCKT NO:** FWLPAT019US
Binie V. Lipps	§	
Frederick W. Lipps	§	**Art Unit:** 1642
	§	
Serial No.: 10/716,982	§	
	§	**Examiner:** Reddig, Peter J.
Filed: November 19, 2003	§	
	§	
For: Saliva test for	§	
early diagnosis of cancers	§	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

Submitted herewith concerning the subject patent application, please find enclosed:

(1) Appellant's Brief on Appeal (31 pages)

(2) a credit card authorization for $270.00, to cover the fee seen due for filing a brief in support of appeal. Applicant is entitled to and asserts small entity status.

Please mail correspondence to:

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Respectfully submitted:

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I hereby certify that this correspondence and all documents referred to herein is being deposited with the United States Postal Service as first class mail in an envelope addressed to the above addressee on

14 October 2008

10-14-08

by John R. Casperson, Reg. No. 28,198 (date)

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APPELLANT'S BRIEF ON APPEAL

This brief is in furtherance of the Notice of Appeal filed in this case on August 14, 2008.

The fees required under 37 CFR 1.17 (c) and any required petition for extension of time for filing this brief and fees therefor are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

STATEMENT OF THE REAL PARTY IN INTEREST

The real party in interest is Binie V. Lipps.

STATEMENT OF RELATED CASES

With respect to other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal: There are no such appeals or interferences

JURISDICTIONAL STATEMENT

This appeal is taken under 35 USC 134(a).

The final rejection from which appeal is taken is dated April 14, 2008, as modified by an advisory action dated September 4, 2008.

The notice of appeal was filed August 14, 2008, together with a request for a one-month extension of time.

This brief is being filed on October 14, 2008.

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Manual of Patent Examining Procedure, Section 2164 page 10

STATUS OF AMENDMENTS

An amendment after final rejection dated June 21, 2008 which canceled claim 18 and amended claim 24 to obviate a rejection under 35 USC 112, second paragraph has been entered per the advisory action dated September 4, 2008 and the claims as reproduced in the appendix incorporate the amendment. The advisory indicates on page 2 that a rejection of claims 1-3, 8-12, 16, 17, 20 and 24 under 35 USC 112, first paragraph, was withdrawn in view of the argument made in the amendment after final. Although the advisory is silent on the point, the examiner indicated in a telephone conversation dated October 14, 2008 that the amendment after final had overcome the rejection of claim 24. These two 35 USC 112 rejections are therefore believed not in issue and are not argued.

GROUNDS OF REJECTION TO BE REVIEWED

Rejection 1: Nonenablement

Claims 1-3, 8-12, 16-18, 20 and 24 stand rejected under 35 USC 112, first paragraph, for failure to comply with the enablement requirement, as set forth in the

Final Rejection dated April 14, 2008, section 6, pages 3-10, and the Advisory Action dated September 4, 2008 page 2.

Rejection 2: Lack of written description

Claims 1-3, 8-12, 16-18, 20 and 24 stand rejected for failure to comply with the written description requirement, as set forth in the Final Rejection dated April 14, 2008, section 7, pages 10-12, and the Advisory Action dated September 4, 2008 page 2.

STATEMENT OF FACTS

The invention relates to screening for early cancers by using a noninvasive saliva test. (Specification, page 1, lines 10-11)

The screening test, which is non-specific for the type of cancer, is conducted by obtaining a saliva specimen from a person to be screened and forming it into a saliva sample. The saliva sample is then brought together with a reagent containing polyclonal antibodies made against a mixture of plurality of proteonic cancer markers from different types of cancer cells to form an assay sample. A determination is then made, for example, by ELISA, as to whether an

immunological reaction has occurred in the assay sample. The occurrence of the immunological reaction is indicative of a positive screening test, especially when the occurrence of reaction is confirmed by ELISA test results above some predetermined value. (Specification, page 4, lines 9-17)

The reagent contains antibodies made against a plurality of proteonic cancer markers, so that the likely presence of any one of several cancers can be determined. This can be accomplished, for example, by immunizing animals with a mixture obtained by combining different proteonic cancer markers from different cancer cell lines. (Specification, Page 5, lines 33-36). The blood containing the polyclonal antibodies is collected from the animals and further separated into a serum containing the polyclonal antibodies from the blood. The reagent is formed from the serum. (Specification, Page 5, lines 17-19)

It is not necessary to know the identity of the antibodies or the identity of the proteonic cancer markers in order to practice the invention. The mixture contains markers identified and markers not yet identified. (Specification, page 7, lines 25-26). The polyclonal antibodies made against the mixture of markers "know" the identity of the proteonic cancer markers they were made against . . . The antibodies

formed against the mixture are reactive with proteonic cancer markers from different cancers and are employed to provide the screening test results.

The proteonic cancer markers are extracted from colonies of cancer cells. The colonies of cancer cells can be formed from publicly available cancer cell lines, for example, a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line. (Specification, Page 5, lines 6-14) The proteonic cancer markers are generally formed by combining at least a portion of the colony of cells with a carrier fluid, agitating the carrier fluid to disrupt the cells and form a suspension, centrifuging the suspension to separate out cell debris and nuclei, and then collecting the supernatant fluid which contains the proteonic cancer marker from the colony. (Specification, Page 5, lines 25-29).

Laboratory results reveal that proteonic cancer markers for breast, colon, liver and ovary can be detected in saliva using the method of the invention (Specification, Page 9, line 34 - Page 10, line 13, Table 2) and that ELISA titers are higher for

persons with known cases of cancer (Specification, Page 12, Table 4) than general population members (Specifications, page 10, Table 2). The data indicate that an ELISA titer of 1,000 is a suitable cutoff for screening test results. (Specification, Page 10, lines 12-15). Followup testing with antibodies formed against non-mixed PCMs can be employed to zero in on the most likely cancer type. (Specification, Page 11, lines 1-9, Table 3).

ARGUMENT

Rejection 1: Nonenablement

Claims 1-3, 8-12, 16-18, 20 and 24 stand finally rejected in Section 6 of the final rejection, appearing on pages 3-10, under 35 USC 112, first paragraph, for failure to comply with the enablement requirement.

Concerning this rejection, claim 1 and its dependent claims 2-3, 8-10, 11-12, 20 and 24 stand or fall separately from independent claim 16 and its dependent claim 17.

Claim 1 recites:

> "providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and

markers not yet identified;" and

"f) assaying the assay sample by simple ELISA test to determine whether an immunological reaction has occurred in the assay sample, wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer."

Whereas claim 16 recites:

"a) providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified;" and

"g) assaying the assay sample by simple ELISA titer test to determine whether an immunological reaction has occurred in the assay sample, wherein ELISA titer test results of greater than 1:1,000 are indicative of a positive screening test for cancer."

It is stated on page 5 of the Final Rejection, first full paragraph, that

"One cannot extrapolate the teaching of the specification to the enablement of the claims because the specification gives insufficient guidance and direction

as to what predetermined value in the ELISA test is indicative of a positive screening test for cancer. . . .the only predetermined value taught in the specification a titer of 1:1000 is not predictably useful for indicating a positive test for cancer as the claimed method gives values above 1:1000 in individuals that are apparently normal and also produces values below 1:1000 in individuals who appear to have cancer . . . "

Appellant first responded to this point in the amendment filed June 21, 2008, pages 8-10. MPEP 2164 discusses the enablement requirement. The factors to be considered are (A) The breadth of the claims (B) The nature of the invention (C) The state of the prior art (D) The level of one of ordinary skill (E) The level of predictability in the art (F) The amount of direction provided by the inventor (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Each of the claims is directed toward "A non-invasive cancer screening method". The difference between a screening method and a diagnostic method is that a screening method assigns nonsymptomatic patients to a risk category, whereas a diagnostic method determines whether or not a patient has a disease. The

arguments set forth in section 6 of the Final Rejection relate largely to diagnostic methods, which is not the nature of the invention. When the claimed screening method is carried out, a patient that has a test result over a predetermined value (for example, 1000) is at higher risk for cancer than a patient that has a test result of less than a predetermined value (for example, less than 1000). As is well known to those skilled in the art, (persons possessing doctorate degrees and several years of experience) the predetermined value can be moved higher to reduce the number of false positive test results, or lower to reduce the number of false negative test results. There is no magic number, and the failure of the specification to provide one does not establish a meritorious case of nonenablement. Based on the description and examples, and the skill level of the art, a suitable predetermined value for the screening test cutoff can be determined without unreasonable experimentation (Claims1-3, 8-10, 11-12 and 20-24), and need not be determined at all for claims 16-17, which state that it is to be 1:1,000.

On page 2 of the advisory action dated September 4, 2008, the examiner states

> "Although the method is drawn to screening and one of skill in the art could adjust the cutoff point to reduce the number of false positive test results, or lower it to reduce the number of false negative test results, given that the

ELISA titers for the proteonic polyclonal antibodies exhibit significant over lap between samples from what appears to be normal individuals, Tables 2 and 3, and cancer patients, Table 4, with titers over 1:1000 in both groups, one of skill in the art would not predictably be able to use the claim methods for cancer screening for the reasons previously set forth."

Appellant has not had opportunity to respond to this. Table 3 is a subset of Table 2. Of the individuals from the general population tested in Table 2, approximately 1/4 had an ELISA titer from the mixed antibodies of the broad claims (PCM mix) of greater than 1:1000, and these patients are further the subjects in Table 3. Of the cancer patients tested in Table 4, 4/5 had an ELISA titer from the mixed antibodies of the broad claims (PCM mix) of greater than 1:1000, the exception being a prostate/vocal cord cancer victim who had undergone treatment. (Specification, pages 9-11). A cursory inspection of the Table 4 data reveals that, with the exception of the prostate/vocal cord cancer victim, the lowest cancer-victim ELISA titer against PCM mix is 1800, and in Table 2, the highest screening-test ELISA titer against PCM mix is 1600, so the examiner's contention that there is significant overlap is misleading. Selecting an ELISA titer of 1700, for example, would provide a clearer numerical demarcation, albeit with the concomitant certainty of a

higher number of false negatives. The appellants selected a cutoff of 1,000 in their experimental. The examiner has not shown that the cutoff fails to divide the population into lower and higher risk portions or that one of skill in the art would not predictably be able to use the claim methods even without a specific numerical limitation for cancer screening.

It was argued in the final rejection dated April 14, 2008, pages 7-10, that the specification is not enabling for using the range of proteonic cancer markers within the scope of the claims, specifically those derived from in vivo sources. Appellant responded in the responsive amendment filed June 21, 2008, as follows:

The examples in the specification show the recovery of proteonic cancer markers used in the making of antibodies from in vitro sources. The claims would include proteonic cancer markers from in vivo sources. Proteonic cancer markers from in vivo sources would be expected to produce more efficacious antibodies for carrying out the invention than those from in vitro sources, since "real life" antigens would produce antibodies which effective against them. The situation is non-analogous to (non-antibody-based) cancer drug efficacy, where in vitro efficacy is not a good predictor of in vivo efficacy. The invention is not an anti-cancer drug. Additionally,

the invention has been demonstrated in a living system, and this is shown in the examples. Because the specification shows antibody operability from PCMs derived from in vitro sources, antibody operability for PCMs derived from in vivo sources is fairly established. It is additionally pointed out presently that claims 16-17 are limited to "providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers" which is closely supported by the experimental data of the application.

The examiner responded on page 2 of the advisory action dated September 4, 2008 as follows:

> "Although antibodies produced proteonic cancer markers from in vivo sources could potentially be used as claimed, the claims are not so limited and, thus, this argument is not found persuasive. Given that the ELISA titers for the proteonic polyclonal antibodies produced from the in vitro cultured cell lines exhibit significant overlap between samples from what appears to be normal individuals, Tables 2 and 3, and cancer patients, Table 4, with titers over 1:1000 in both groups, one of skill in the art would not predictably be able to use the claimed methods for cancer screening for the reasons previously set forth."

Appellant has not had opportunity to respond to this. The nature of the invention is cancer screening, as contrasted to cancer treatment. The chemical reactions occur in vitro, rather than in vivo, with the exception of polyclonal antibody production, and more predictable than in vivo reactions. The examiner advances no reason to doubt that proteonic cancer markers could not be obtained from in vivo produced cancers, or that those PCMs from in vivo sources would not result in the production of polyclonal antibodies, i.e., that those steps would be unpredictable. In view of the nature of the invention, the relative predictability of the chemistry involved, and the skill of the art, it is submitted that claims are enabled and the examiner's rejection is in error and should be reversed.

Rejection 2--Lack of written description

Claims 1-3, 8-12, 16-18, 20 and 24 stand finally rejected in Section 7 of the final rejection, appearing on pages 10-12, for failure to comply with the written description requirement.

Concerning this rejection, claim 1 and its dependent claims 2-3, 8-10, 11-12, 20 and 24 stand or fall separately from independent claim 16 and its dependent claim 17.

Claim 1 recites

"providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified".

Claim 16 recites:

"a) providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified;"

On page 11 of the final rejection, it is stated

"Because the genus of a mixture from different types of cancer cells containing proteonic cancer markers identified and markers not yet identified is not adequately described, the method claims relaying on said genus are also not adequately described."

On page 12 of the Final Rejection, it is stated

"the genus is only described as a definition by function (i.e. the ability to form polyclonal antibodies), and beyond that example of a mixture of markers from the HT-29/breast cancer, Diji/colon cancer, CCL-13/liver, and Sk-ov-

3/ovarian cancer cells, one of skill in the art cannot readily visualize or recognize the identity of members of the genus."

It is stated on page 11 of the final rejection that

"One of skill in the art can reasonably conclude that applicant was not in possession of a genus of "a mixture from different types of cancer cells containing proteonic cancer markers identified and markers not yet identified" at the time the invention was filed."

Appellant responded to this in the amendment filed June 21, 2008 as follows: The recitation of the "genus" in the claims must be evaluated in view of the prior art and the level of skill in the art in order to determine whether it is adequately disclosed. Claim 1 recites: "providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified". Different types of cancer cells were known to the art. It was known that cancer cells produced proteonic cancer markers, some of which were known and others not. What was not known was putting these proteonic cancer markers in a mixture. The level of skill in the art is mostly likely a doctorate degree and several years of research experience. Making a mixture of known materials is well within the level of skill. Furthermore, the specification

provides a description of 4 "species" within the "genus" and demonstrates operability for them, and these are set forth in claim 16 as "a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified" so at least claim 16 should be in compliance. The specification furthermore mentions at page 5, lines 9-14 that the

> "cell line can be selected from the group consisting of a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line."

Because of these factors, and because of the disclosure of representative species over the scope of the claims, it is submitted that all claims are in compliance with the written description requirement.

It is stated on page 2 of the advisory action dated September 4, 2008 that

> "...the proteonic markers for making the mixture are not known in the art or taught by the specification. Although cancer cells were known in the art and

one of skill in the art could make a mixture of lysates from those cells which would potentially contain the claimed known and unknown proteonic marks, the claims are not limited to mixtures of cancer cell lysates. Thus, given cancer cell, even specific cancer cell types, contain a myriad of potential known and unknown proteonic markes, none of which have been identified, one of skill in the art could not readily visualize the claimed genus, for the reasons previously set forth."

Appellant has not had opportunity to respond to this before. The specification demonstrates in the examples that appellant had possession of an embodiment of the invention within the scope of the claims. How to make the markers is taught. How to use the markers to make the necessary antibodies is taught. How to use the antibodies to conduct a screening test is taught. No reason has been advanced to doubt that appellant failed to do what is described in the examples, and the examples fairly support the constructive reduction to practice that is described in the specification. The specification as a whole would allow one of ordinary skill in the art to recognize that appellant invented what is claimed. Further, the level of skill and knowledge in the art is such that one would be able to follow the detailed steps of the claimed methods. The practice of the method requires no knowledge of the

structures and properties of a compound that would predictably result in the desired activity; rather, the claimed invention is a screening method, not the compounds screened for or the compounds employed in the screening. Thus, one of ordinary skill in the art would conclude that appellant was in possession of the claimed method of screening for cancers at the time of filing.

The Lilly case is not on point, as the unsupported (and un-described) "genus" there was a generically claimed, inadequately characterized, composition of matter which was asserted to be novel. The present claims are methods, and the materials employed are known and/or obtainable using the teaching of the specification and characterized functionally and by way of example.

In the advisory action dated September 4, 2008, it is stated:

> ". . .the proteonic markers for making the mixture are not known in the art or taught by the specification and thus, one of skill in the art could not readily visualize the claimed genus."

This is appellants' first opportunity to respond to this point. It is not necessary to know what the markers are in order to practice the claimed method. One must

know how to obtain and use the markers, and this is taught by the specification.

In view of the forgoing remarks, it is submitted that the rejection for lack of a written description is in error and should be reversed.

CONCLUSION AND SIGNATURE BLOCK

In view of the forgoing arguments, reversal of all grounds of rejection is requested.

Respectfully submitted:

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AN APPENDIX CONTAINING A CLAIMS SECTION, A CLAIM SUPPORT AND DRAWING ANALYSIS SECTION, A MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION, AN EVIDENCE SECTION, AND A RELATED CASES SECTION

CLAIMS SECTION

1. (rejected) A noninvasive cancer screening method comprising

a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified;

b) forming polyclonal antibodies against the mixture;

c) forming a reagent from said polyclonal antibodies;

d) obtaining a saliva sample from a human not diagnosed with cancer;

e) bringing said saliva sample together with the reagent to form an assay sample, and

f) assaying the assay sample by simple ELISA test to determine whether an immunological reaction has occurred in the assay sample,

wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer.

2. (Rejected) A method as in claim 1

wherein, in the ELISA test, the human saliva sample is coated on a plate prior to being brought together with the reagent.

3. (Rejected) A method as in claim 2 wherein the ELISA test results are titer.

4 - 7 (canceled)

8. (Rejected) A method as in claim 1 wherein the polyclonal antibodies are produced in animals.

9. (Rejected) A method as in claim 8 further comprising separating blood containing the polyclonal antibodies from the animals and separating serum

containing the polyclonal antibodies therefrom.

10. (Rejected) A method as in claim 9 further comprising forming the reagent from the serum.

11. (Rejected) A method as in claim 1 further comprising centrifuging a human saliva specimen to separate out cells and mucin and collecting the supernatant to form the human saliva sample.

12. (Rejected) A method as in claim 11 further comprising collecting the human saliva specimen.

13 - 15 (canceled)

16. (Rejected) A non-invasive cancer screening method comprising

a) providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, said mixture containing proteonic cancer markers identified and markers not yet identified;

b) forming polyclonal antibodies against the mixture;

c) forming a reagent from said polyclonal antibodies;

d) obtaining a saliva specimen from a human not diagnosed with cancer;

e) forming a saliva sample from the saliva specimen;

f) bringing the saliva sample together with the reagent to form an assay sample; and

g) assaying the assay sample by simple ELISA titer test to determine whether an immunological reaction has occurred in the assay sample,

wherein ELISA titer test results of greater than 1:1,000 are indicative of a positive screening test for cancer.

17. (Rejected) A method as in claim 16

wherein, in the simple ELISA test, the saliva sample is coated on a plate prior to

being brought together with the reagent .

18 - 19. (canceled)

20. (Rejected) A method as in claim 1 further comprising, in a case where the ELISA test results are indicative of a positive screening test for cancer,

a) obtaining a second saliva specimen from the human,

b) forming a second saliva sample from the second saliva specimen,

c) separating the second saliva sample into a plurality of portions,

d) bringing each portion of the second saliva sample together with a reagent produced by providing a mixture of proteonic cancer markers identified and markers not yet identified from a single type of cancer cells, forming polyclonal antibodies against the mixture, and forming the reagent from the polyclonal antibodies, to form an assay sample; and

e) conducting a simple ELISA test on the assay sample,

wherein an ELISA test result higher than a predetermined value is indicative of a positive screening test for proteonic markers of said cancer cell type.

21 - 23 (canceled)

24. (Rejected) A method as in claim 20

wherein the single type of cancer cells is selected from the group consisting of a breast cancer cell line, a lung cancer cell line, a stomach cancer cell line, a liver cancer cell line, a colon cancer cell line, an ovarian cancer cell line, a cervical cancer cell line, a mouth/pharynx cancer cell line, a skin cancer cell line, a pancreatic cancer cell line, a testes cancer cell line, a brain tumor cell line, and a prostate cancer cell line .

A CLAIM SUPPORT AND DRAWING ANALYSIS SECTION

1. (rejected) A noninvasive cancer screening method ({**page 4, line 9**}) comprising

a) providing a mixture of proteonic cancer markers from different types of cancer cells, said mixture containing proteonic cancer markers identified and markers not yet identified;({**page 7, lines 25-26**});

b) forming polyclonal antibodies against the mixture; ({**page 5, lines 33-36**})

c) forming a reagent from said polyclonal antibodies; ({**page 5, lines 17-19**})

d) obtaining a saliva sample from a human not diagnosed with cancer ({**page 4, lines 9-11**});

e) bringing said saliva sample together with the reagent to form an assay sample, ({**page 6, lines 4-6**)}) and

f) assaying the assay sample by simple ELISA test to determine whether an immunological reaction has occurred in the assay sample,({**page 6, lines 11-15**}).

wherein ELISA test results higher than a predetermined value are indicative of a positive screening test for cancer ({**page 6, lines 11-15**}).

16. (Rejected) A non-invasive cancer screening method ({**page 4, line 9**}) comprising

a) providing a mixture of proteonic cancer markers obtained from breast, liver, colon, and ovarian cancers, ({**page 7, lines 25-26**}) said mixture containing

proteonic cancer markers identified and markers not yet identified ({**page 7, lines 25-26**});

b) forming polyclonal antibodies against the mixture; ({**page 5, lines 33-36**})

c) forming a reagent from said polyclonal antibodies ({**page 5, lines 17-19**});

d) obtaining a saliva specimen from a human not diagnosed with cancer ({**page 4, lines 9-11**});

e) forming a saliva sample from the saliva specimen;({**page 4, lines 9-11**})

f) bringing the saliva sample together with the reagent to form an assay sample; ({**page 4, lines 11-13**}) and

g) assaying the assay sample by simple ELISA titer test to determine whether an immunological reaction has occurred in the assay sample,({**page 6, lines 11-15**})

wherein ELISA titer test results of greater than 1:1,000 are indicative of a positive

screening test for cancer. ({**page 10, lines 11-12**})

20. (Rejected) A method as in claim 1 further comprising, in a case where the ELISA test results are indicative of a positive screening test for cancer, ({**page 6, liens 14-15**})

a) obtaining a second saliva specimen from the human, ({**page 6, line 18**})

b) forming a second saliva sample from the second saliva specimen, ({**page 6, line 18**})

c) separating the second saliva sample into a plurality of portions, ({**page 6, line 18**})

d) bringing each portion of the second saliva sample together with a reagent ({**page 6, lines 19-20**}) produced by providing a mixture of proteonic cancer markers identified and markers not yet identified ({**page 7, lines 25-26**}); from a single type of cancer cells, forming polyclonal antibodies against the mixture, and forming the reagent from the polyclonal antibodies, to form an assay sample; ({**page 6, lines 18-23, page 7, lines 25-28**}) and

e) conducting a simple ELISA test on the assay sample,

wherein an ELISA test result higher than a predetermined value is indicative of a positive screening test for proteonic markers of said cancer cell type. ({**page 6, lines**

11-15})

A MEANS OR STEP PLUS FUNCTION ANALYSIS SECTION

None.

AN EVIDENCE SECTION

None.

A RELATED CASES SECTION

None.